President) 1 Memorial Drive, Kansas City, Missouri, 64198–0001. Comments can also be sent electronically to *KCApplicationComments@kc.frb.org:*

1. *The Marital Trust created under Indenture of the James S. Birkbeck Revocable Trust, dated April 20, 1995, Holton, Kansas, Paula Birkbeck Taylor, Holton, Kansas, and J. Patrick Birkbeck, Topeka, Kansas, as co-trustees; Paula N. Birkbeck Taylor Revocable Trust UIT dated August 8, 2002, Holton, Kansas, Paula Birkbeck Taylor, as trustee; Paula Birkbeck as co-trustee of the Mary Lou Birkbeck Trust dated April 20, 1995, Holton, Kansas; J. Patrick Birkbeck Revocable Trust UIT dated March 31, 2008, Topeka, Kansas, J. Patrick Birkbeck, as trustee; and Ryan Patrick Taylor, Holton, Kansas;* to become members of the Birkbeck/Taylor Family Control Group, a group acting in concert, to retain voting shares of Denison Bancshares, Inc. of Holton, and thereby indirectly retain voting shares of Denison State Bank, both of Holton, Kansas.

Board of Governors of the Federal Reserve System.

Michele Taylor Fennell,

Deputy Associate Secretary of the Board.

[FR Doc. 2023–27357 Filed 12–12–23; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Interstate Administrative Subpoena and Notice of Lien (Office of Management and Budget OMB #: 0970–0152)

AGENCY: Office of Child Support Services, Administration for Children and Families, U.S. Department of Health and Human Services.

ACTION: Request for public comments.

SUMMARY: The Administration for Children and Families (ACF) is requesting a 3-year extension with proposed revisions to the Interstate Administrative Subpoena and Notice of Lien forms (Office of Management and Budget #0970–0152, expiration 6/30/2024). The forms are updated to reflect the name change of the Federal child support program office from the Office of Child Support Enforcement to the Office of Child Support Services.

DATES: *Comments due within 60 days of publication.* In compliance with the requirements of the Paperwork Reduction Act of 1995, ACF is soliciting public comment on the specific aspects of the information collection described above.

ADDRESSES: You can obtain copies of the proposed collection of information and submit comments by emailing *infocollection@acf.hhs.gov.* Identify all requests by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Administrative Subpoena is used by State child support agencies to obtain income and other financial information regarding noncustodial parents for purposes of establishing, enforcing, and modifying child support orders. The Notice of Lien imposes liens in cases with overdue support and allows a State child support agency to file liens across State lines, when it is more efficient than involving the other State's IV–D agency.

Section 452(a)(11) of the Social Security Act requires the Secretary of the Department of Health and Human Services to promulgate forms for administrative subpoenas and imposition of liens used by State child support agencies in interstate cases. Section 454(9)(E) of the Social Security Act requires each State to cooperate with any other State in using the Federal forms for issuance of administrative subpoenas and imposition of liens in interstate child support cases.

Respondents: State, local, or Tribal agencies administering a child support program under title IV–D of the Social Security Act.

ANNUAL BURDEN ESTIMATES

Instrument	Annual number of respondents	Annual number of responses per respondent	Average burden hours per response	Annual burden hours
Administrative Subpoena	54	462	.5	12,474
Notice of Lien	54	29,762	.5	803,574

Estimated Total Annual Burden Hours: 816,048.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 42 U.S.C. 652; 42 U.S.C. 654.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2023–27313 Filed 12–12–23; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–D–4974]

Advanced Manufacturing Technologies Designation Program; Draft Guidance for Industry; Availability; Agency Information Collection Activities; Proposed Collection; Comment Request

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the availability of a

draft guidance for industry entitled ''Advanced Manufacturing Technologies Designation Program.'' FDA encourages the early adoption of advanced manufacturing technologies (AMTs) that have the potential to benefit patients by improving manufacturing and supply dependability and optimizing development time of drug and biological products. These technologies can be integral to ensuring quality and supporting a robust supply of drugs that are life-supporting, life-sustaining, of critical importance to providing healthcare, or in shortage. AMTs can directly improve product quality through higher capability manufacturing designs and enhanced controls (*e.g.,* leading to fewer human errors). This draft guidance provides recommendations to persons and organizations interested in participating in FDA's Advanced Manufacturing Technologies Designation Program, which is intended to facilitate the development of drugs, including biological products, manufactured using an AMT that has been designated as such under the program.

DATES: Submit either electronic or written comments on the draft guidance by February 12, 2024 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance. Submit electronic or written comments on the proposed collection of information in the draft guidance by February 12, 2024.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–D–4974 for ''Advanced Manufacturing Technologies Designation Program.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002; or the Office of Communication, Outreach and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT:

With regard to the draft guidance: Ranjani Prabhakara, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 75, Rm. 6648, Silver Spring, MD 20993, 240–402–4652; or Anne Taylor, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

With regard to the proposed collection of information: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Advanced Manufacturing Technologies Designation Program.'' On December 29, 2022, the Food and Drug Omnibus Reform Act of 2022 (FDORA) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 506L (21 U.S.C. 356l), which requires the establishment of an Advanced Manufacturing Technologies Designation Program and the publication of a related guidance. FDA's

Advanced Manufacturing Technologies Designation Program offers a framework for persons or organizations (*e.g.,* applicants, contract manufacturers, technology developers) to request designation of a method or combination of methods of manufacturing a drug as an AMT. The program is intended to facilitate the development of drugs that are manufactured using a designated AMT, submitted in an application under section 505 of the FD&C Act (21 U.S.C. 355) or section 351 of the Public Health Service Act (PHS Act) (42 U.S.C. 262), and regulated by the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER). FDA will expedite development and assessment of an application, including supplements, for drugs that are manufactured using a designated AMT as described in section 506L(d)(1) of the FD&C Act.

The development of this guidance takes into consideration feedback provided at a public meeting (see section 506L(e) of the FD&C Act) and comments submitted to the public docket (Docket No. FDA–2023–N–1259) about the public meeting. The meeting was held on June 8, 2023 (April 24, 2023, 88 FR 24807), to discuss the use of innovative manufacturing technologies for CDER- and CBER-regulated products and to solicit industry and public feedback regarding the Advanced Manufacturing Technologies Designation Program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on ''Advanced Manufacturing Technologies Designation Program.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Advanced Manufacturing Technologies Designation Program

OMB Control Number 0910–0139—Revision

This information collection supports implementation of requirements under section 506L of the FD&C Act. The Advanced Manufacturing Technologies Designation Program encourages early adoption of new technological advances in manufacturing processes by the pharmaceutical industry or other drug/biologic developers to ensure that regulatory assessments and new drug and biologic development are based on state-of-the-art pharmaceutical science. Any request for AMT designation will be reviewed by a team of FDA experts in quality assessment to evaluate the data and information submitted and to determine if the method of manufacturing or combination of methods meets the criteria of an AMT in section 506L of the FD&C Act. If AMT designation is granted, then future new drug application (NDA), abbreviated new drug application (ANDA), or biologics license application (BLA) applicants may use or reference the designated AMT, noting specific application of the designated AMT to specific product development and inclusion in NDA, ANDA, or BLA submissions describing development and manufacturing processes.

We are issuing a draft guidance for industry entitled ''Advanced Manufacturing Technologies Designation Program,'' which outlines the process for submitting an AMT designation request; when and how FDA will communicate receipt of and provide advice on AMT designation requests; when and how FDA will assess AMT designation requests; the process by which FDA will engage with designated AMT holders and applicants for drugs manufactured using, referencing, or relying upon a designated AMT; and benefits related to drug development and application assessment.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Section 506L of the FD&C Act	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
AMT designation request; Guidance for industry section III.B	20	1	20	10	200
Total	.....	.....	20	.....	200

[1] There are no capital or operating and maintenance costs associated with the information collection.

This draft guidance also refers to previously approved FDA collections of information. The collections of information in 21 CFR part 312 regarding product development including chemistry, proposed manufacturing procedures and controls, and requests for meetings have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 regarding applicable manufacturing information for NDAs are approved under OMB control number 0910–0001; and the collections of information in 21

CFR part 601 regarding applicable manufacturing information for BLAs are approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at *https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Dated: December 8, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–27309 Filed 12–12–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–5022]

Data Standards; Support and Requirement Begins for the Clinical Data Interchange Standards Consortium Version 2.0 of the Study Data Tabulation Model, Version 3.4 of the Study Data Tabulation Model Implementation Guide, and Version 1.0 of the Standard for Exchange of Nonclinical Data Implementation Guide—Genetox; Requirement Ends for the Clinical Data Interchange Standards Version 3.2 of the Study Data Tabulation Model Implementation Guide

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA or Agency) Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER) are announcing that support begins for version 2.0 of the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTMv2.0), version 3.4 of the CDISC Study Data Tabulation Model Implementation Guide (SDTMIGv3.4), and version 1.0 of the Standard for Exchange of Nonclinical Data Implementation Guide—Genetox (SENDIG-Genetoxv1.0) and announcing the date that these version updates are required in certain submissions. CBER and CDER are also announcing the date that requirement ends for version 3.2 of the CDISC SDTMIG (SDTMIGv3.2). The Agency will update the FDA Data Standards Catalog (Catalog) to reflect these changes. The Agency will publish in the technical specifications document entitled ''Study Data Technical Conformance Guide'' additional details on how to implement new variables.

DATES: Support for version CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 begins December 13, 2023.

The requirement for electronic submissions to be submitted using CDISC SDTMv2.0, SDTMIGv3.4, and SENDIG-Genetoxv1.0 begins March 15, 2025, for new drug applications (NDAs), abbreviated new drug applications (ANDAs), certain biologics license applications (BLAs), and certain investigational new drug applications (INDs). The requirement for electronic submissions to be submitted using version CDISC SDTMIGv3.2 ends December 13, 2023.

ADDRESSES: You may submit comments as follows.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2023–N–5022 for ''Data Standards; Requirement Begins for the Clinical Data Interchange Standards Consortium Version 2.0 of the Study Data Tabulation Model and Version 3.4 of the Study Data Tabulation Model Implementation Guide; Requirement Ends for the Clinical Data Interchange Standards Version 3.2 of the Study Data Tabulation Model Implementation Guide.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the